English Synopsis

I. Title of Study

Effect of non-nutritive sucking on feeding intolerance in premature Infants

II. Indication

To study the effect of non-nutritive sucking on feeding intolerance in premature infants.

III. Phase of Development:

This is a study for a master thesis. Not applicable.

IV. Study Rationale:

Premature babies are defined as babies born alive before 37 weeks of pregnancy. There was 10.5% preterm of whole pregnancy in Taiwan, including 9.14% low birth weight (LBW) who born weighting between 1500-2499 g and 1.02% very low birth weight (VLBW) who born weighing under 1500 g. Generally, more early gestational ages and lower birth weight accompany more problems. They need to accept professional supervision, monitoring, and caring to maintain their growth in the neonatal intensive care unit (NICU). Premature infants need a progressive nasogastric tube diet to meet their nutritional needs due to the immature gastrointestinal tract. However, feeding intolerance, such as gastric residual volume (GRV), meteorism, and milk regurgitation, is also increased due to an immature, less functional gastrointestinal tract. This symptom will result in less feeding or fasting, which makes premature infants cannot get enough enteral nutrition and extrauterine growth restriction (EUGR). Although there is no standard guideline for relieving feeding intolerance symptoms and providing enough nutrients until now, non-nutritive sucking (NNS) was thought to have the benefit premature infants. It can stabilize an infant's emotions, and physiological condition, relieve pain, promote the development of sucking, increase the efficacy of oral feeding, decrease the time of nasogastric tube feeding and shorten the hospital stay. This study wants to evaluate whether the different times of NNS before feeding can decrease the incidence of feeding intolerance.

V. Study Objectives:

To evaluate whether non-nutritive sucking before oral feeding can reduce the feeding intolerance, such as gastric residual volume (GRV), meteorism, and

milk regurgitation.

VI. Study Design

- Duration of Treatment
  3 days

- Number of Planned Patients
  180 participants, 146 evaluable participants.
  - Birth between Week (26-27)+6 days:
    Experiment A group:30, Experiment B group:30, Control group: 30
  - Birth between Week (28-31)+6 days, above :
    Experiment A group:30, Experiment B group:30, Control group: 30

- Investigational Product
  Not applicable.

- Endpoints
  Primary endpoint:
  To evaluate whether non-nutritive sucking before oral feeding can reduce the feeding intolerance, such as gastric residual volume (GRV), meteorism, and milk regurgitation, compared to no intervention.

  Secondary endpoint:
  To evaluate whether 5 minutes of non-nutritive sucking before oral feeding can reduce the feeding intolerance, such as gastric residual volume (GRV), meteorism, and milk regurgitation, better than 15 minutes of non-nutritive sucking before oral feeding.

- Criteria for Evaluation
  The full analysis set (FAS) means all the data of a participant was collected and an intent-to-treat set (ITT) means data of a participant with at least 4 interventions was collected. The primary and secondary endpoints will be analyzed by a FAS and an ITT.

- Statistical Methods

  For the primary and secondary endpoint, all the data will be checked their normal distribution by Kolmogorov-Smirnov analysis to determine whether to use parametric or nonparametric statistics. The difference in gastric residual volume (GRV), meteorism, and milk regurgitation between the NNS intervention and no intervention will be analyzed by the generalized estimating equations of SPSS 21, α value will be set at 0.05.

- Duration of the Study

  2022/07/01 to 2024/06/30, a total of 2 years.

- End of Study

  The sponsor reserves the right to terminate the study, according to the master thesis progression. The sponsor may terminate the study due to the following situations:

  i. The master thesis topic is changed.
  ii. The data show a significant result to the hypothesis, although the recruited number does not reach 180.

  The investigator should notify the IRB in writing of the study's completion or early termination and send a copy of the notification to the sponsor.